UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APR 17 1996

#14

Antoinette F. Konski
MORRISON & FOERSTER
755 Page Mill Road
Palo Alto, CA 94304

In re TheraTech Inc.
U.S. Patent No. 4,983,395 : ORDER TO SHOW CAUSE

An application for extension of the patent term of U.S. Patent No. 4,983,395, which issued January 8, 1991, under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on November 24, 1995. Extension is sought based upon the premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a product identified as ANDRODERM®.

The application raises a question of eligibility for patent term extension of a patent where the active ingredient of the drug product (ANDRODERM®) claimed[1] by the patent has been previously approved for commercial marketing and use by the Food and Drug Administration (FDA).

ANDRODERM® is a human drug product[2] that was approved for commercial marketing and use by the FDA on September 29, 1995. ANDRODERM® is a transdermal delivery system for the steroid testosterone.

The FDA has advised the PTO that the active ingredient (testosterone) had been approved for commercial marketing and use by the FDA prior to the approval of ANDRODERM®. In a letter dated February 22, 1996, the PTO was also advised that the products: ORETON-F OINTMENT, PERANDRENAL OINTMENT, MALE SEX HORMONE INJECTION, TESTRYL INJECTION, TRIPLE HORMONE SUSPENSION/INJECTION, MYOSOL TESTOSTERONE, TESTODERM TESTOSTERONE TRANSDERMAL SYSTEM, and TESTOSTERONE had been approved prior to the approval of ANDRODERM®. (Copy enclosed)

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, inter alia, the product has been subject to a regulatory review period before its commercial

---

[1] As the independent claim of the patent broadly recites "active agent" the claim is construed to cover the presence of all active agents (active ingredients) identified in the application.

[2] "Drug products" undergo a regulatory review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA). "Medical devices" undergo a review under § 515 of the Act.

marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 4,983,395 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) defines a "drug" as "(B) articles intended for use in the diagnosis, cure, mitigation or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man other animals . . . but does not include devices or their components, parts, or accessories."

Section 201(h) of the FFDCA defines "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component, part of accessory, . . . which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

Section 201(p) of the FFDCA defines "new drug" as:

> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective . . . or
> (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, has been used to a material extent or for a material time under such conditions.

Since the product ANDRODERM® achieves its principal intended purpose through chemical

action within the body of a human and since it was not generally recognized as safe and effective, but because of investigations has become so recognized, the product is a "new drug" as used in the FFDCA and 35 U.S.C. § 156 and not a device as defined in § 201(h).

By the explicit terms of § 156(f)(2), the term "product" as it relates to a drug product means the active ingredient of the new drug product. The active ingredient of the drug product is testosterone. As noted in the above FDA letter, the active ingredient testosterone had been approved for commercial marketing and use prior to the approval of applicant's product. Applying the definition of "product" provided in § 156(f) to the extension requirement of § 156(a)(5)(A), applicant's approved product ANDRODERM® does not qualify as the first permitted marketing or use of the active ingredient. Compare In re Fisions Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd. Fisons plc. v. Quigg, 10 USPQ2d 1869 (Fed. Cir. 1988) (copies enclosed).

In view of all the above, it appears that the patent is not eligible for extension of its term under 35 U.S.C. § 156(a)(5)(A).

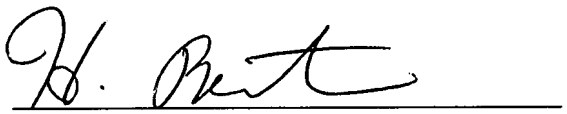
ORDER

Applicant is hereby given ONE (1) MONTH from the date of this order to show cause why the PTO should not issue a decision denying the application for patent term extension on the ground that the permission of commercial marketing and use of applicant's product was not the first permitted commercial marketing and use of the active ingredient of the approved product. The provisions of 37 CFR § 1.136(a) do not apply to the one month period.

Any response should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box DAC Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries should be directed to the undersigned at (703) 305-9285.



Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: RONALD L. WILSON, DIRECTOR (without attachments)
HEALTH ASSESSMENT POLICY STAFF
OFFICE OF HEALTH AFFAIRS (HFY-20)
FOOD AND DRUG ADMINISTRATION
5600 FISHERS LANE, ROOM 11-44
ROCKVILLE, MD 20857

RE: ANDRODERM® (testosterone)
FDA DOCKET NO: 95E-0420

kt